§317.400 Exemption from nutrition labeling.

(a) * * *

(1) Food products produced by small businesses, other than the major cuts of singleingredient, raw meat products identified in §317.344 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in §317.301 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with §317.362(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

(7) * * *

(iii) Products that are ground or chopped at an individual customer's request.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS: REINSPECTION AND PREPARATION OF PROD-**UCTS**

Subpart A—General

Sec.

318.1 Products and other articles entering official establishments.

318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.

318.3 Designation of places of receipt of products and other articles for reinspec-

318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

318.5 Requirements concerning procedures.

318.6 Requirements concerning ingredients and other articles used in preparation of products.

318.8 Preservatives and other substances permitted in product for export only; handling; such product not to be used for domestic food purposes.

318.9 Samples of products, water, dyes, chemicals, etc., to be taken for examina-

318.10 Prescribed treatment of pork and products containing pork to destroy trichinae.

318.11 [Reserved]

318.12 Manufacture of dog food or similar uninspected article at official establishments.

318.13 Mixtures containing product but not amendable to the Act.

318.14 Adulteration of product by polluted water; procedure for handling.

318.15 Tagging chemicals, preservatives, cereals, spices, etc., "U.S. retained."

318.16 Pesticide chemicals and other residues in products.

318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.

318.18 Handling of certain material for mechanical processing.

318.19 Compliance procedure for cured pork products.

318.20 Use of animal drugs.

318.21 [Reserved]

318.22 Determination of added water in cooked sausages.

318.23 Heat-processing and stabilization requirements for uncured meat patties.

318.24 Product prepared using advanced meat/bone separation machinery; process control.

Subparts B-F [Reserved]

Subpart G—Canning and Canned **Products**

318.300 Definitions.

318.301 Containers and closures. 318.302 Thermal processing.

318.303 Critical factors and the application of the process schedule.

318.304 Operations in the thermal processing area. 318.305 Equipment and procedures for heat

processing systems. 318.306 Processing and production records.

318.307 Record review and maintenance.

318.308 Deviations in processing.

318.309 Finished product inspection.

Personnel and training. 318.310

318.311 Recall procedure.

AUTHORITY: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

Subpart A—General

Source: 35 FR 15586, Oct. 3, 1970, unless otherwise noted.

§318.1 Products and other articles entering official establishments.

(a) Except as otherwise provided in paragraphs (g) and (h) of this section or §318.12, no product shall be brought into an official establishment unless it has been prepared only in an official establishment and previously inspected and passed by a Program employee, and is identified by an official inspection legend as so inspected and passed.

§318.1

Notwithstanding the foregoing provisions of this subparagraph, product imported in accordance with part 327 of this subchapter and not prepared in the United States outside an official establishment, may enter any official establishment subject in other respects to the same restrictions as apply to domestic product. Products received in an official establishment during the Program employees absence shall be identified and maintained in a manner acceptable to such employee. Product entering any official establishment shall not be used or prepared thereat until it has been reinspected in accordance with §318.2. Any product originally prepared at any official establishment may not be returned into any part of such establishment, except the receiving area approved under §318.3, until it has been reinspected by the inspector.

(b) No slaughtered poultry or poultry product shall be brought into an official establishment unless it has been (1) previously inspected and passed and is identified as such in accordance with the requirements of the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) and the regulations thereunder, and has not been prepared other than in an establishment inspected under said Act, or (2) has been inspected and passed and is identified as such in accordance with the requirements of a State law.

(c) Every article for use as an ingredient in the preparation of meat food products, when entering any official establishment and at all times while it is in such establishment, shall bear a label showing the name of the article, the amount or percentage therein of any substances restricted by this part or part 317 of this subchapter, and a list of ingredients in the article if composed of two or more ingredients: Provided. That in the case of articles received in tank car lots, only one such label shall be used to identify each lot. In addition, the label must show the name and address of the shipper.

(d) To ensure the safe use of preparations used in hog scalding water or in the denuding of tripe, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any lim-

itations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B, or 9 CFR Chapter III, Subchapter A or Subchapter E.

(e) Dyes, chemicals, or other substances the use of which is restricted to certain products may be brought into or kept in an official establishment only if such products are prepared thereat. No prohibited dye, chemical, preservative, or other substance shall be brought into or kept in an official establishment.

(f) [Reserved]

(g) Glands and organs, such as cotyledons, ovaries, prostate glands, tonsils, spinal cords, and detached lymphatic, pineal, pituitary, parathyroid, suprarenal, pancreatic and thyroid glands, used in preparing pharmaceutical, organotherapeutic, or technical products and which are not used as human food (whether or not prepared at official establishments) may be brought into and stored in edible product departments of inspected establishments if packaged in suitable containers so that the presence of such glands and organ will in no way interfere with the maintenance of sanitary conditions or constitute an interference with inspection. Glands or organs which are regarded as human food products, such as livers, testicles, and thymus glands, may be brought into official establishments for pharmaceutical, organotherapeutic or technical purposes, only if U.S. inspected and passed and so identified. Lungs and lung lobes derived from livestock slaughtered in any establishment may not be brought into any official establishment except as provided §318.12(a).

(h)(1) Carcasses of game animals, and carcasses derived from the slaughter by any person of livestock of his own raising in accordance with the exemption provisions of paragraph 23(a) of the Act, and parts of such carcasses, may be brought into an official establishment for preparation, packaging, and storing in accordance with the provisions of §303.1(a)(2) of this subchapter.

(2) Meat, meat byproducts, and meat food products bearing official marks showing that they were inspected and passed under State inspection in any State not designated in §331.2 of this subchapter may be received by official establishments for storage and distribution solely in intrastate commerce. The presence of such State inspected products must not create any unsanitary condition or otherwise result in adulteration of any products at the official establishment or interfere with the conduct of inspection under this subchapter. In addition, such State inspected products must be stored separately and apart from the federally inspected products in the official establishment.

- (i) The operator of the official establishment shall furnish such information as is necessary to determine the origin of any product or other article entering the official establishment. Such information shall include, but is not limited to, the name and address of the seller or supplier, transportation company, agent, or broker involved in the sale or delivery of the product or article in question.
- (j) Any product or any poultry or poultry product or other article that is brought into an official establishment contrary to any provision of this section may be required by the Administrator to be removed immediately from such establishment by the operator thereof, and failure to comply with such requirement shall be deemed a violation of this regulation. If any slaughtered poultry or poultry products or other articles are received at an official establishment and are suspected of being adulterated or misbranded under the Poultry Products Inspection Act or the Federal Food, Drug, and Cosmetic Act, or applicable State laws, the appropriate governmental authorities will be notified.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 38 FR 5152, Feb. 26, 1973; 48 FR 6091, Feb. 10, 1983; 49 FR 32055, Aug. 10, 1984; 64 FR 72174, Dec. 23, 1999]

§318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.

(a) All products and all slaughtered poultry and poultry products brought into any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment and shall be subject to reinspection by a

Program employee at the official establishment in such manner and at such times as may be deemed necessary to assure compliance with the regulations in this subchapter.

- (b) All products, whether fresh, cured, or otherwise prepared, even though previously inspected and passed, shall be reinspected by Program employees as often as they may deem necessary in order to ascertain that they are not adulterated or misbranded at the time they enter or leave official establishments and that the requirements of the regulations in this subchapter are complied with.
- (c) Reinspection may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The circuit supervisor shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.¹
- (d) A U.S. retained tag shall be placed by a Program employee at the time of reinspection at any official establishment on all products which are suspected on such reinspection of being adulterated or misbranded, and such products shall be held for further inspection. Such tags shall be removed only by authorized Program employees. When further inspection is made, if the product is found to be adulterated, all official inspection legends or other official marks for which the product is found to be ineligible under the regulations in this subchapter, shall be removed or defaced and the product will be subject to condemnation and disposal in accordance with part 314 of this subchapter, except that a determination regarding adulteration may be deferred if a product has become

¹Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisors of Program circuits. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved, such as liver, oxtails,